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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/922,619	08/06/2001	Richard Apodaca	ORT-1474	8473

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EXAMINER

WRIGHT, SONYA N

ART UNIT	PAPER NUMBER
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1626

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DATE MAILED: 03/07/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/922,619

Applicant(s)

APODACA ET AL.

Examiner

Sonya Wright

Art Unit

1626

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-60 is/are pending in the application.
- 4a) Of the above claim(s) 47,52-55 and 60 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 50 and 59 is/are rejected.
- 7) ☒ Claim(s) 1-46, 48-51, and 56-59 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) Z.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

### **DETAILED ACTION**

This is a response to Applicant's remarks filed 11-25-02. Claims 1-60 are pending in this application.

The objection to claims 1-46, 48-51 and 56-59 for containing non-elected subject matter has been maintained. The rejection under 35 U.S.C. 103 has been withdrawn. The rejection of claims 50 and 59 under 35 U.S.C. 112 have been maintained. The rejection of claim 51 under 35 U.S.C. 112 has been overcome with Applicant's amendment. Claims 47, 52-55, and 60 are withdrawn from consideration.

### ***Claim Objections***

Claims 1-46, 48-51 and 56-59 drawn to compounds and methods of use wherein G and W are piperazine and morpholine and all other variables are as defined, has been examined. Claims 1-46, 48-51 and 56-59 are objected to for containing non-elected subject matter. For example, claim 1 defines variables R6-R10, L6 and L7, which do not appear in the structure of the compound of formula (I). The claims also contain variables such as L1, L2, L3, Q, G, etc. . . which do not appear in the structure of the compound of formula (I). It is requested that Applicant limit claims 1, 7-20, 23-32, 34, 35, 39-43, and 46 to the elected subject matter in order to overcome this objection. Please note that claim 15 should be limited to "morpholinyl" instead of unsubstituted or substituted morpholinyl, so that claim 15 will contain subject matter which is supported in claim 1.

Claim 51 is objected to as being dependent upon rejected claim 50.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 59 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. For rejections under 35 U.S.C. 112, first paragraph, the following factors must be considered (In re Wands, 8 USPQ2d 1400, 1404 (CAFC, 1988)):

- 1) Nature of invention.
- 2) State of prior art.
- 3) Level of ordinary skill in the art.
- 4) Level of predictability in the art.
- 5) Amount of direction and guidance provided by the inventor.
- 6) Existence of working examples.
- 7) Breadth of claims.

8) Quantity of experimentation needed to make or use the invention based on the content of the disclosure.

Claim 59 is directed to "the prevention of upper airway allergic response, nasal congestion, allergic rhinitis". The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention

Art Unit: 1626

commensurate in scope with these claims. It has not been shown in the specification that the testing protocol used is accepted in the art as being predictive of the alleged utility. There are a vast number of of upper airway allergic response, nasal congestion, allergic rhinitis related disorders and applicant does not give support for the prevention of all forms of these disorders. The art pertaining to of upper airway allergic response, nasal congestion, allergic rhinitis remains highly unpredictable. The various forms of these disorders have different causative agents, involve different cellular mechanisms, and, consequently, differ in treatment protocol. Therefore, based on the unpredictable nature of the invention and state of the prior art and the extreme breadth of the claims, one skilled in the art could not use the claimed invention without undue experimentation.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 50 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 50 is drawn to a "method of treating a subject having a disease or condition modulated by histamine H3 receptor activity". The term "modulate" renders the claim indefinite. "Modulate" means that a histamine H3 receptor can both inhibit and cause a disease or condition. It is unclear whether Applicant claims that the role of histamine H3 is to inhibit or to cause a disease or condition.

***Response to Arguments***

Applicant's arguments, see page 10, lines 8-24, page 11 in its entirety, and page 12, lines 1 and 2, filed 11-25-02, with respect to the rejection under 35 U.S.C. 103 have been fully considered and are persuasive.

Applicant's arguments filed 11-25-02 regarding the objection to claims containing non-elected subject matter, the rejection of claims 50 and 59 under 35 U.S.C. 112 have been fully considered but they are not persuasive. Regarding the objection to claims containing non-elected subject matter, the amendments to claims 1, 4-6, 15, 33, 36, 44, 45, 49, 50, and 56-59 have not overcome the objection. It is requested that Applicants limit claims 1, 7-20, 23-32, 34, 35, 39-43, and 46 as set forth in the "Claim Objections" supra. Please note that in the previous Office Action claim 47 was objected to for containing non-elected subject matter in error. Claim 47 was withdrawn in the last Office Action and should not have been objected to.

Regarding the rejection of claim 59 under 35 U.S.C. 112, Applicant argues that the kinds of congestion in claim 59 are known to be susceptible of prevention, and that such a utility is therefore not incredible on its face. Further, Applicants respectfully submit that the data presented in the application is sufficient to support the H3 antagonism activity of the claimed compound, and therefore supports the method of preventing upper airway allergic response, nasal congestion, or allergic rhinitis, as claimed. However, There are a vast number of upper airway allergic response, nasal congestion, and allergic rhinitis related disorders and Applicant does not give support for the prevention of all forms of these disorders. Applicant gives only general

Art Unit: 1626

information regarding the use of the instant compounds in the Background Information section, in pages 51-58 in their entirety. Applicant shows limited biological methods on page 137-139 which do not support a claim drawn to the prevention of all forms of upper airway allergic response, nasal congestion, and allergic rhinitis. The various forms of these disorders have different causative agents, involve different cellular mechanisms, and consequently, differ in treatment protocol. Therefore, based on the unpredictable nature of the invention and the extreme breadth of the claims, one skilled in the art could not use the claimed invention without undue experimentation.

It is suggested that Applicants delete "or preventing" from claim 59 in order to obviate this rejection under 35 U.S.C. 112.

Regarding the rejection of claim 50 under 35 U.S.C. 112, Applicants argue that they do not claim methods of causing undesirable diseases or conditions, and that the compounds of the application have been shown to modulate histamine H3 receptor, and therefore are suitable for treating disease or conditions that are affected by modulation of the histamine H3 receptor. However, the term modulate is indefinite and it is unclear what diseases or conditions can be treated with the claimed invention. Since claim 51 lists diseases "modulated by histamine H3 receptor activity", it is suggested that Applicant incorporate 51 into claim 50 and delete claim 51.

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within

Art Unit: 1626

TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sonya Wright, whose telephone number is (703) 308-4539. The examiner can normally be reached on Monday-Friday from 8:00 AM - 5:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. Joseph K. McKane, can be reached at (703) 308-4537. The Unofficial fax phone number for this Group is (703) 308-7922. The Official fax phone numbers for this Group are (703) 308-4556 or 305-3592.

When filing a FAX in Technology Center 1600, please indicate in the Header (upper right) "Official" for papers that are to be entered into the file, and "Unofficial" for draft documents and other communications with the PTO that are not for entry into the file of the application. This will expedite processing of your papers.

Communications via Internet e-mail regarding this application, other than those under 35 U.S.C. 132 or which otherwise require a signature, may be used by the applicant and should be addressed to [joseph.mckane@uspto.gov]. All Internet e-mail communications will be made of record in the application file. PTO employees will not communicate with applicant via Internet e-mail where sensitive data will be exchanged or where there exists a possibility that sensitive data could be identified unless there is



Art Unit: 1626

of record an express waiver of the confidentiality requirements under 35 U.S.C. 122 by the applicant. See the Interim Internet Usage Policy published by the Patent and Trademark Office Official Gazette on February 25, 1997 at 1195 OG 89.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist, whose telephone number is (703) 308-1235.



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Joseph K. McKane

Supervisory Patent Examiner

Group 1600

Sonya Wright

February 27, 2003